UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,464	11/09/2001	Warren L. Vanhout	P-10154	5011

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EXAMINER
SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Application No.	Applicant(s)
10/008,464	VANHOUT, WARREN L.
Examiner	**Art Unit**	
Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.
2a) ☐ This action is **FINAL**.   2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-49* is/are pending in the application.
    4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) *21-25 and 31-34* is/are allowed.
6) ☒ Claim(s) *1-10,13-18,26,28-30,35-43 and 46-49* is/are rejected.
7) ☒ Claim(s) *11,12,19,20,27,44 and 45* is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a)☐ All   b)☐ Some * c)☐ None of:
      1.☐ Certified copies of the priority documents have been received.
      2.☐ Certified copies of the priority documents have been received in Application No. _____.
      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date *4/5.*
4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that
form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public
> use or on sale in this country, more than one year prior to the date of application for patent in the United
> States.

2.   Claims 1, 7, 15, 16, 26, 28-30, 35-37, 39, 47 are rejected under 35 U.S.C. 102(b)
as being anticipated by Struble et al. (Pat. No. 6,070,101).

        Concerning claim 1 and claims with similar limitations, the method of Corbucci
includes providing cardiac resynchronization to a heart during a first time period (the
time period occurring after expiration of the AV delay and during stimulation), and
refraining from providing cardiac resynchronization to the heart during a second time
period (the time period prior to expiration of the AV delay). A related comment applies
to claims 26 and 39.

        In regards to claims 7, 15 and 16, note col. 3, lines 37-48.

3.   Claims 1-10, 13-18, 26, 28-30, 35-43 and 46-49 are rejected under 35
U.S.C. 102(b) as being anticipated by Tockman et al. (Pat. No. 5,540,727).

        Regarding claim 1 and claims with similar limitations, Tockman et al. teach to
provide cardiac resynchronization therapy (bi-ventricular pacing) to a heart during a first
time period (see col. 3, lines 38-42, col. 5, lines 19-27, etc.), and refrains from providing
resynchronization therapy during a second time period (i.e., when a mode other than bi-
ventricular pacing is selected, and/or the time delay associated with block 62 of the
flowchart shown in Fig. 2).

        Regarding claim 2 and claims with similar limitations, the examiner considers the
first time period representing activation of the bi-ventricular mode to occur during a
fraction of a day, with the day inherently equaling the first time period plus the second
time period (i.e., during the course of any given day, performance of the algorithm set
forth in Fig. 2 will naturally consist of a time when the bi-ventricular mode is active, and
a time when such a mode is inactive or refrained).

Regarding claim 3 and claims with similar limitations, one can consider Tockman et al. to define three time periods in any given day, with the first time period relating to the time it takes to test the efficiency of the bi-ventricular mode, the second time period relating to the time where modes other than the bi-ventricular mode are being tested, and the third time period relating to the time where the optimal mode is discovered to be the bi-ventricular mode and the pacer is accordingly reset to bi-ventricular pacing after all other modes have been tested.

Regarding claim 4 and claims with similar limitations, Tockman et al. disclose the step of commencing cardiac resynchronization at a first reference time (e.g., after an AV delay period, and/or after the expiration of set time periods T, and synchronized to the respiratory cycle), and provides cardiac resynchronization during a third time period commencing at a second reference time (e.g., after all modes have been used and the pacer is programmed to operate in bi-ventricular mode).

In reference to claim 5 and claims with similar limitations, the examiner considers the test time period (i.e., the time period required for the pacer to loop once through the algorithm shown in Fig. 2 while executing the bi-ventricular pacing mode) to precede the third time period (i.e., the time period during which the pacer is programmed to operate outside of the testing period in a bi-ventricular mode). The time set aside for testing is inherently shorter than the time set for steady-state operation.

Concerning claims 6 and 8, note block 58 of Fig. 2 which instructs the pacer to set the pacing mode in at least one instance to bi-ventricular pacing commencing at the first reference time as discussed above, and blocks 108 and 110 which instruct the pacer to enter the third time period commencing at the second reference time as also discussed above.

Claim 7 is clearly anticipated.

Regarding claim 9 and claims with similar limitations, one of the possible modes of operation during the second time period consists of delivering a pacing pulse to a single chamber of the heart (note for example col. 3, lines 37-43).

Regarding claim 10 and claims with similar limitations, Tockman et al. disclose mode b3 wherein a sensed atrial event initiates bi-ventricular stimulation. Tockman et

al. also disclose that a DDD pacer may be employed and operated in a variety of modes such as VDD wherein by definition of the third letter "D", stimulation is inhibited upon the detection of a sensed event. Furthermore, the term "sensed event" is broad enough to include the sensing of control signals by the processor indicative of the need to change pacing modes (note elements 102 and 104 of Fig. 2). Switching from a bi-ventricular pacing mode to a single chamber pacing mode upon sensing a "NO" event in the "USED ALL MODES" decision box would result in refraining from providing cardiac resynchronization therapy.

Regarding claims 17 and 48, Tockman et al. disclose sensing an atrial event, incrementing a counter thereafter (note instruction 104 of Fig. 2) and determining whether a bi-ventricular pace is indicated based on the counter.

Regarding claim 38, the examiner considers the device of Tockman et al. to comprise memory that stores parameters for determining whether cardiac resynchronization is indicated by virtue of the fact that in order to answer the question posed in block 102 by the algorithm shown in Fig. 2, the system must comprise such a memory. Furthermore, one could say that the parameters stored in block 82 of the algorithm are used to determine which mode is optimal and therefore can be used to determine whether resynchronization is indicated (i.e., it is indicated if it is the most optimal treatment based on an analysis of the stored parameters, but not indicated if it is determined to be less than optimal).

Allowable Subject Matter

4.   Claims 11, 12, 19, 20, 27, 44 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Concerning claim 11 and those claims pertaining to a ratio of X:Y, the prior art of record does not appear to teach the receipt of such a ratio where cardiac resynchronization is performed X times for every Y sensed cardiac events.

Regarding claim 20, the prior art of record does not appear to disclose the step of receiving a time period and indicating bi-ventricular pacing for atrial events occurring within this time period.

Regarding claim 27, the prior art of record does not appear to disclose the use of memory for storing the duration of the first period during which resynchronization is applied. There is no teaching to modify the operation of the Tockman et al. or Struble et al. systems to include such memory.

5.   Claims 21-25 and 31-34 are allowed.
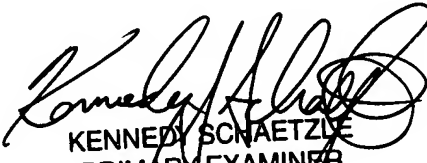
Conclusion

6.   The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
March 26, 2004

KENNEDY SCHAETZLE
PRIMARY EXAMINER